PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JMCV0330.PCT	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/GB2004/001336	International filing date *(day/month/year)* 29.03.2004	Priority date *(day/month/year)* 27.03.2003
International Patent Classification (IPC) or national classification and IPC A61H23/04, A61H9/00		
Applicant BRISTOL-MYERS SQUIBB COMPANY ET AL.		

1. This report is the International preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27.01.2005	07.03.2005
Name and mailing address of the International preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Oelschläger, H Telephone No. +31 70 340-1968

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/001336

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-11 as originally filed

   Claims, Numbers

   1-17 filed with telefax on 27.01.2005

   Drawings, Sheets

   1/3-3/3 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 14-17

because:

☒ the said international application, or the said claims Nos. 14-17 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 14-17

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7
	No:	Claims	1-6, 8-13
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-13
Industrial applicability (IA)	Yes:	Claims	1-13
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The features of claims 14-17 relate to a method of using the compression device of claim 1. These claims relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Moreover, claims 14-17 correspond to original claims 16-19 which were not searched (Rule 39.1(iv) PCT).

   In view of that the substantive examination cannot be performed for these claims . Consequently, no opinion will be formulated with respect to novelty, inventive step and the industrial applicability of the subject-matter of claims 14-17 (Articles 34(4)(a)(I) and (ii) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Reference is made to the following documents:
   - D1: US-A-4 624 244 (TAHERI SYDE A) 25 November 1986 (1986-11-25)
   - D3: US-B1-6 440 093 (NAKANE JONATHAN J ET AL) 27 August 2002 (2002-08-27)
   - D5: US-A-4 054 129 (BYARS EDWARD F ET AL) 18 October 1977 (1977-10-18)

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

   The document D1 discloses (see col. 1, line 31 - col. 4, line 42, and figures 1-4; the references in parenthesis applying to this document) a compression device (10) suitable for the limb of a mobile patient comprising an inflatable sleeve (11, 13) adapted to surround the limb, a conduit (53, 55, 57, 60) attached to said sleeve (11, 13) suitable for delivering fluid to said sleeve, a portable or wearable controller (66, 72) attached to the conduit (53, 55, 57, 60) that generates and controls the flow of

fluid in the device (10), wherein the sleeve (11, 13) comprises a leg cuff (13) and a foot cuff (11) and the leg cuff (13) comprises at least three cells (B-D).

Also document D3, col. 3, line 46 - col. 12, line 26, and fig. 1A-2, discloses all features of claim 1. The subject-matter of claim 1 is therefore not new in the sense of Article 33(2) PCT.

3. The device disclosed in claim 1 is industrial manufacturable and therefore the requirements of Article 33(4) PCT are met.

4. Dependent claims 2-13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see e.g. documents D1, D3 and D5.

Novelty:
document D1, col. 1, line 31 - col. 4, line 42, and fig. 1-3, for claims 2, 4-6, 8, 10, 11 and 13,
document D3, col. 3, line 46 - col. 12, line 26, and fig. 1A-2, for claims 3, 9 and 12.
Inventive step:
document D5, col. 2, line 47 - col. 5, line 8, and fig. 1-5, for claim 7.

5. Dependent claims 2-13 refer to further embodiments of the concept of claim 1 and therefore meet the requirements of Article 33 (4) PCT for the same reasons given above.

CLAIMS:

1. A compression device for the limb of a mobile patient comprising:

an inflatable sleeve adapted to surround the limb;

a conduit attached to the sleeve for delivering fluid to the sleeve; and

a portable, wearable controller attached to the conduit that generates and controls the flow of fluid in the device

wherein the sleeve comprises a leg cuff and a foot cuff and the leg cuff comprises at least three cells.

2. A compression device as claimed in claim 1 characterised in that the controller comprises a microprocessor control system and a pump.

3. A compression device as claimed in claim 1 or claim 2 characterised in that the device comprises at least one pressure sensor associated with the sleeve.

4. A compression device as claimed in any preceding claim characterised in that the sleeve comprises one or more individually inflatable cells.

5. A compression device as claimed in any preceding claim characterised in that the sleeve is low profile and discrete.

6. A compression device as claimed in any preceding claim characterised in that the leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or foot which have the greatest effect on blood flow.

7. A compression device as claimed in any preceding claim characterised in that the device further comprises a sock interposed between the sleeve and the limb.

8. A compression device as claimed in any preceding claim characterised in that the controller is battery operated.

9. A compression device as claimed in any preceding claim characterised in that each cell is monitored by a sensor.

10. A compression device as claimed in claim 1 characterised in that the cells are a gaiter cell, adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell, adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell adapted to wrap around the lower limb in the region between the mid-calf cell and the knee.

11. A compression device as claimed in any preceding claim where the cells may be pressurised to the same or different predetermined pressures.

12. A compression device as claimed in any preceding claim where the pressure in the device is monitored during use to provide a dynamic compression.

13. A compression device as claimed in claim 12 where the pressure in the device increases when the patient stands.

14. Use of a compression device as claimed in claim 1 in the prevention or treatment of venous insufficiency.

15. Use of a compression device as claimed in claim 1 in the prevention or treatment of oedema.

16. Use of a compression device as claimed in claim 1 in the treatment of DVT.

17. Use of a compression device as claimed in claim 1 in the prevention of postthrombotic syndrome.